REMARKS/ARGUMENT

Description of Amendments

Claims 28, 44, 45 and 54 are amended, Claims 1-27, 29-43, 46-49, 51 and 53 are canceled and new Claims 55-61 presented. Claims 28, 44 and 55 are the independent claims.

Support for new claim 55 may be found at paragraph [0056] of U.S. Pub. No. 2004/0186553. Support for new claims 59-60 may be found at paragraphs [0006] and [0038].

Duty of Disclosure

Applicants would like to bring to the Examiner's attention the following patent applications: 11/840,147; 12/184,347; 10/880,025; 10/235,033 (now U.S. Patent No. 6,723,120); 08/837,993 (now U.S. Patent No. 6,240,616); and 11/173,713. The current application is a divisional of the '033 application. Applicants assume that the Examiner, for consistency in examination by the Office, will coordinate the examination of the current application with these other applications.

Rejection under 35 U.S.C. § 103

Claims 28, 41, 53, 29 stand rejected under 35 USC § 103(a) as unpatentable over *Schwartz* (US5607463) taken alone or in combination with *Macgregor* (US4458366).

Schwartz is concerned with forming a layer of biocompatible material over a polymer core layer of a medical device to avoid adverse reactions between the polymer and blood and/or vascular tissue. *See* col. 2, ll. 22-25 and 49-52. The disclosure concludes that improved biocompatibility can be achieved if a thin layer of metal is applied to the base material, i.e., a polymer base layer. "To accomplish this, the metal layer is less than 3000 angstroms thick". Col. 2, l. 64 to col. 3, l. 13. The layer is made very thin so that it will not inhibit the stent from being expanded. Col. 3, ll. 39-43.

Schwartz's stent referred to in the Official Action consists of a thin elastomeric film supported by a wire structure. The very thin metallic layer is then deposited over the elastomeric film to improve biocompatibility. Col. 7, ll. 25-45. The resulting coated stent may have

perforations in it so that a drug held in the polymeric inner core layer can be eluted through the perforations. Alternatively, a drug-polymer coating can be applied over the surface of the metal outer coating.

Referring now to the Official Action, the Office concludes that it would have been obvious to use sintered particles or filaments in place of the deposition technique taught in *Schwartz*. The rationale advanced in support of the rejection under 35 U.S.C. § 103(a) is that one of ordinary skill would have recognized the suitability for using sintered particles, in place of a PVD coating process, to form the metallic layer in *Schwartz* to achieve an intended purpose. *Macgregor* is cited for the teaching of forming a layer of sintered particles on a medical device. The sintered particles are formed from a roughening of a base metal layer, then sintering the particles produced from this roughening to the remaining base metal layer in a later step.

Applicants respectfully traverse.

Claim 28 is directed a strut element of a balloon-expandable stent. The structure of the strut element is formed from a metallic sheet that is metal throughout: a solid metallic inner core, an outer layer being a first porous layer of metallic material formed by particles, filaments or fibers sintered to the inner core, and an inner layer being a second porous layer of metallic material formed by particles, filaments or fibers sintered to the inner core.

Claim 44 is also directed to a strut element of a balloon-expandable stent. This claim recites a metallic sheet having opposed ends and forming a cylinder, the sheet including a solid metallic core and porous metallic layers formed by particles, filaments or fibers sintered to opposite sides of the core, wherein one or more therapeutic agents are impregnated within the porous metallic layers.

The metal coating in *Schwartz*, which is being identified with the claimed porous layers, is not attached to a metallic core. As explained above, *Schwartz* discloses a wire stent that is covered by a polymeric film. The purpose of this disclosure is to describe how a thin metal coating is deposited on a polymeric film, because *Schwartz* wishes to avoid an adverse reaction between blood or vascular tissue and the polymeric material. The polymeric material

layer or core of the stent to which the metal coating is applied, therefore, is an essential part of *Schwartz*. Without the polymer layer, there would be no reason to apply a metal coating.

***Schwartz* does not teach or suggest a stent strut having a core and porous layers formed from a metallic sheet.** As best understood, the "sheet" identified in *Schwartz*, page 2, paragraph 2 of the Official Action, is presumably the polymeric film with metal coating and the wire structure that provides the structural support for the stent. Claim 28, however, recites that the strut is formed from a metallic sheet. *Schwartz* shows a polymeric film supported by a wire structure. *Schwartz* does not teach a strut formed from a metallic sheet.

***Schwartz* does not teach or suggest a therapeutic agent impregnated within a porous metallic layer.** Here the Office points to the passages in *Schwartz* in which a drug-polymer coating is applied over the metal coating, or perforations are made in the metal coating so that a drug in the polymeric film can be released. Col. 3, l. 34 to col. 4, l. 9. However, in none of these examples does *Schwartz* teach or suggest a metal coating that is porous (to the contrary, a "very thin" layer measured in angstroms is not porous for purposes of holding a therapeutic agent), much less impregnating a therapeutic agent within a porous metal layer as claimed.

Schwartz's device cannot be altered to have sintered particles in place of a PVD coating according to Macgregor because Schwartz requires that the metal coating be applied directly to a polymeric surface. The sintering process relied on in *Macgregor*, as discussed above, requires a metal surface for the medical device that is roughened to produce the particles that will later be sintered to the surface. *See* col. 8, l. 36 through col. 10, l. 51. *Schwartz*'s number-one objective is to cover a polymer film with a metal coating to avoid an adverse reaction between blood or vascular tissue and the polymeric material. Without the polymer base layer, there is no reason to apply a metal coating. And without a metal base layer the *Macgregor* method is not possible.

A *prima facie* case of obviousness is not present in *Schwartz* taken alone or in combination with *Macgregor*. *Schwartz* does not teach a porous inner and outer metallic layer attached to a metallic core, a strut formed from a metallic sheet, an agent impregnated within a porous metallic layer, nor is it possible to apply the *Macgregor* method to *Schwartz*'s polymeric

film. **As best understood**, the Official Action found that *Schwartz* either disclosed or rendered obvious each of the above features of the claims. And that *Macgregor*, which has nothing to do with a balloon-expandable stent, or a drug-eluting medical device, is being used simply for the teaching of sintering particles to form a porous outer layer.

A rejection under 35 U.S.C. § 103(a) cannot be sustained on the basis of prior art that does not at least show each element of a claim, or without an adequate explanation for why, despite the absence of an express teaching in the art, a claim would have nonetheless been obvious to one of ordinary skill in the art at the time of the invention. *See KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 1741 (2007). *Schwartz* does not teach, nor suggest alone or in combination with other art of record a porous inner and outer metallic layer attached to a metallic core, a strut formed from a metallic sheet, nor an agent impregnated within a porous metallic layer. Nor does the art of record teach how particles are sintered to *Schwartz*'s polymeric film. And the Office advances no reasons why, despite the absence of express teachings in the art of record, the claims would nonetheless have been obvious to one of ordinary skill in the art at the time of the invention.

The rejections under Section 103 therefore cannot be sustained. Withdrawal of the rejections of Claims 28 and 44 under 35 U.S.C. § 103(a) is appropriate. Allowance of Claims 28, 44 and the claims dependant therefrom are earnestly solicited in view of the foregoing remarks.

To the extent the above has not clearly demonstrated the non-obviousness of Applicant's invention over the art of record, Applicant kindly asks for some clarification as to why the Office found that the combination of *Macgregor* and *Schwartz* is justified on the basis of a suitability of an intended purpose. The "purpose" is not identified in the Office Action. Why would one of ordinary have concluded, or how does the cited art evidence that one of ordinary skill would have recognized the suitability for an "intended purpose" in view of a prior art sintering process, as opposed to a PVD coating that is "so very thin", *Schwartz* at col. 3, ll. 39-42.

Since the Office has not articulated what the intended purpose would have been, Applicants assume it would have been a purposes articulated in *Schwartz*. That is, Applicants understand the Office based its rejection on the view that one of ordinary skill would

have recognized the suitability of sintering particles to the polymeric film of *Schwartz*, in place of the disclosed PVD process (or one of the other disclosed coating processes) to produce a more biocompatible outer surface for an expandable stent structure.

The decision to reject Applicants' claims appears to have been motivated by impermissible hindsight gleaned from Applicants' disclosure. There are at least two instances of *Schwartz* teaching away from the modification relied on to support the rejection. Additionally, the art relied on to reject the claims bears a striking resemblance to the art addressed in Applicant's background of invention.

In *Schwartz*, a metallic layer is formed by physical vapor deposition (PVD), which involves depositing individual atoms or ions of the metal material in order to create an extremely thin metallic layer that has virtually no effect on the mechanical properties of the stent but improves the stent's biocompatibility. *Schwartz* states: "Preferably, the layer is less than about 3000 angstroms thick and most preferably less than 1000 angstroms thick so that the mechanical properties of the base material are not materially affected during the operation of the device by the presence of the metal layer" (*Schwartz* col. 5, lines 52-57). In contrast, *MacGregor* teaches that sintering metallic particles can be used to create a porous surface having "a thickness of less than about 500 microns, preferably about 25 to about 300 microns" (*MacGregor* col. 3, lines 29-31). The preferred sintered thickness of 300 microns is about 3000 times[1] thicker than 1000 angstroms and is 1000 times thicker than 3000 angstroms. The low-end sintered thickness of 25 microns is about 250 times thicker than 1000 angstroms and over 80 times thicker than 3000 angstroms. A person of ordinary skill in the art would believe that increasing the outer layer thickness of the *Schwartz* device to these extremes (*e.g.*, over 80 times thicker), based on the record, would materially affect the mechanical properties of the base material and operation of *Schwartz*'s expandable stent structure. Even the size of individual metallic particles that are sintered in *MacGregor* are much greater than the preferred thickness of Schwartz's outer layer. In particular, *MacGregor* teaches that metal particles used in the sintering process have sizes that

are on the order of several to hundreds of microns in size (*MacGregor* col. 4, lines 13-21). For example, a metal particle that is 10 microns in size is itself 100 times thicker than the 1000-angstrom thickness taught in *Schwartz*. The replacing of a very thin metal coating according to *Schwartz* with a relatively thick porous layer according to *Macgregor* is therefore contrary to *Schwartz*'s desire, as well as any other designer of an expandable stent for delivery inside a body, to maintain flexibility in the stent structure so that it can expand properly and also maintain essentially the same delivery profile before/after the modification is made to the stent.

Additionally, and as noted earlier, the *Macgregor* process requires a base metal layer, as opposed to a polymeric base layer. As best understood, the Office concluded, nevertheless, that one of ordinary skill would have recognized that a metal base layer could be used in place of the polymeric layer since *Macgregor*'s process could be used in place of PVD. Once again, the combination of the art used to justify the claim rejections fundamentally renders inoperable the device sought by *Schwartz*: maintain a delivery profile and flexibility so that it can be expanded, and a stent having a polymeric film, supported by a wire structure and coated with a metal layer to improve its acceptance in the body.

Applicants have thus shown two examples of how *Schwartz* teaches-away from the combination alleged in the Office Action. "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 1740 (2007). "There is no suggestion to combine, however, if a reference teaches away from its combination with another source." *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley, 27 F.3d 551, 553, 31 U.S.P.Q.2D (BNA) 1130, 1131 (Fed. Cir. 1994)*. "If when combined, the references 'would produce a seemingly

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[1] 300 microns ($3x10^{-5}$ meters) divided by 1,000 angstroms ($1x10^{-7}$ meters) equals 3000.

inoperative device,' then they teach away from their combination". *Tec Air*, 192 F.3d at 1360; *see also In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. (BNA) 1125, 1127 (Fed. Cir. 1984)* (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose). *See* MPEP § 2142 (basic requirements for a *prima facie* case of obviousness). For these additional reasons, the claims would not have been obvious over the art of record.

An inspection of Applicant's motivation for the claimed invention further supports the view that the rejection was impermissibly influenced by Applicant's disclosure. The Office's rejection is based on the same art that Applicant found contains shortcomings that can be overcome by the claimed invention. In particular, in paragraph [0006] of the disclosure, Applicants explain that stent designs such as that disclosed in *Schwartz* were inferior, mainly because they used an inner polymer layer:

> stents of polymeric materials have been reinforced with metal structure. These stent designs have the strength necessary to hold open the lumen of the vessel because of the reinforced strength of the metal. Stents made of both polymeric material and metal have a larger radial profile because the volume occupied by the metal portion of the stent cannot absorb and retain drugs. <u>Reducing the profile of a stent is preferable because it increases the in vivo diameter of the lumen created by the stent. Thus it is desirable to configure a metallic stent to deliver drugs to the blood vessel walls without substantially increasing the profile of the stent. The present invention meets these needs</u>.

It is desirable to have sufficient strength in the stent structure, but also with a porosity in this structure to load it with a therapeutic agent while maintaining a low profile. A stent having a metallic core and porous metallic outer layers serves this purpose because it provides the necessary strength, low profile and pores for carrying a therapeutic agent:

> <u>The advantage of the stent 12 of the present invention over prior art medicated stents is one of profile and strength</u>. Metal, including sintered metal, is stronger than synthetic materials that are capable of being loaded with a therapeutic agent. Thus, in order for a medicated stent to deliver an appropriate amount of a therapeutic agent and structurally maintain vessel patency, the profile of the stent must be substantially larger than metal stents.

Paragraph [0038].

For the foregoing reasons Applicants respectfully ask that all standing rejections of the Claims be withdrawn and the claims allowed.

New Claim 55 is directed to a stent comprising a strut element, wherein the strut element includes a network of attached particles forming a porous metallic core of the strut element, a first porous metallic layer of attached particles disposed over a first portion of the porous metallic core of the strut element, and a third porous metallic layer of attached particles disposed over a second portion of the porous metallic core of the strut element, wherein the average pore size of the metallic core is greater than the average pore size of the second porous layer and the third porous layer, and wherein the stent is configured for being radially expanded by a balloon and for providing support to a body vessel after the stent has been radially expanded by the balloon. None of the art of record teach or suggest at least a core having an average pore size greater than an average pore size of second and third outer layer. Allowance of new Claim 55 is earnestly solicited.

Conclusion

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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